

WO9934850

Publication Title:

DEVICE FOR CONTROLLING THE PENETRATION DEPTH OF A NEEDLE,
FOR APPLICATION TO AN INJECTION SYRINGE

Abstract:

Abstract of WO9934850

The invention relates to a device for controlling or adjusting the penetration depth of a needle, specifically designed for application to an injection syringe, comprising an element designed for contacting a person's skin, said contact element including a surface which encompasses, at least partially, the tip of the needle. The contact element is operatively associated with syringe coupling means and comprises a plurality of throughgoing micro-holes passing through the surface.

Data supplied from the esp@cenet database - Worldwide abc

Courtesy of <http://v3.espacenet.com>

Best Available Copy

This Patent PDF Generated by Patent Fetcher(TM), a service of Stroke of Color, Inc.

PCT

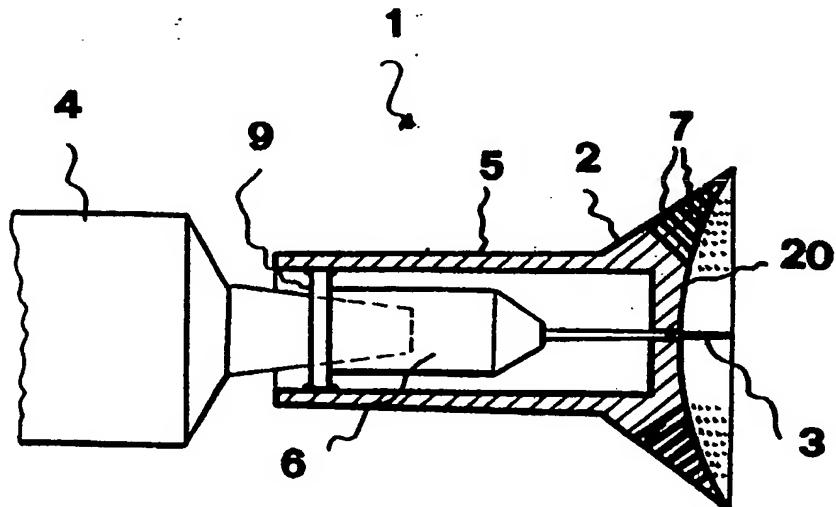
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 5/46	A1	(11) International Publication Number: WO 99/34850 (43) International Publication Date: 15 July 1999 (15.07.99)
(21) International Application Number: PCT/IT98/00262		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
(22) International Filing Date: 2 October 1998 (02.10.98)		
(30) Priority Data: MI98A000009 8 January 1998 (08.01.98) IT		
(71) Applicant (for all designated States except US): FIDERM S.R.L. [IT/IT]; Via Matteotti, 48, I-20064 Gorgonzola (IT).		
(72) Inventor; and		
(75) Inventor/Applicant (for US only): DI PIETRO, Antonino [IT/IT]; Via Plinio, 1, I-20129 Milano (IT).		
(74) Agent: CICOGNA, Franco; Ufficio Internazionale Brevetti Dott. Prof. Franco Cicogna, Via Visconti di Modrone, 14/A, I-20122 Milano (IT).		

(54) Title: DEVICE FOR CONTROLLING THE PENETRATION DEPTH OF A NEEDLE, FOR APPLICATION TO AN INJECTION SYRINGE



(57) Abstract

The invention relates to a device for controlling or adjusting the penetration depth of a needle, specifically designed for application to an injection syringe, comprising an element designed for contacting a person's skin, said contact element including a surface which encompasses, at least partially, the tip of the needle. The contact element is operatively associated with syringe coupling means and comprises a plurality of throughgoing micro-holes passing through the surface.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	IU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		

Description

DEVICE FOR CONTROLLING THE PENETRATION DEPTH OF A NEEDLE, FOR APPLICATION TO AN INJECTION SYRINGE

BACKGROUND OF THE INVENTION

The present invention relates to a device for controlling the penetration depth of a needle, for application to an injection syringe.

5 As is known, several substances are conventionally injected into the human body, for example intracutaneously, i.e. by injections which affect substantially only the surface layer of the human derma.

10 In particular, for performing the above mentioned injections, it is necessary to cause a syringe needle to enter for a limited length the patient derma.

15 On the other hand, as prior syringes are used for the above mentioned application, it is difficult to obtain a proper penetration depth of the needle, since this penetration depth substantially depends on the manual skillness of the operator.

20 In this connection, it should be apparent that an excessive penetration of the syringe needle would originate a disagreeable pain feel for the patient, while preventing the injected substance from being properly absorbed.

25 A further aspect to be considered is that intradermal injection treatments, such as, in particular, those of a dermatological type, would require a comparatively high number of intradermal or

intracutaneous injections, thereby the above mentioned problems will recursively occur.

SUMMARY OF THE INVENTION

5 Accordingly, the aim of the present invention is to provide a device for controlling or adjusting the penetration depth of a syringe needle, which is specifically designed for application to an intradermal injection syringe, which allows the 10 injections to be performed in an optimum manner.

The above aim is achieved by the present invention providing a device for controlling the penetration depth of a needle, for application to an injection syringe, characterized in that said device 15 comprises a skin contacting element, said skin contacting element including a surface encompassing, at least partially, the tip of said needle, and in that said skin contacting element is operatively associated with coupling means for connection with 20 said syringe.

According to a preferred embodiment of the present invention, the skin contacting element comprises an end tapering portion ending with the above mentioned surface.

25 Preferably, said surface has a spherical cap configuration and has its concavity facing the needle tip.

Moreover, the needle tip projects for a short length from said surface.

30 According to a further preferred embodiment of the present invention, the mentioned end tapering portion is provided with a plurality of throughgoing

holes passing through said surface.

According to a further preferred embodiment of the invention, the means for coupling the skin contacting element and syringe comprise an outer cylindric body ending with said tapering portion and an inner cylindric body, substantially coaxial to the outer cylindric body supporting the syringe needle.

Finally, the inner cylindric body comprises a circular rim or edge, opposite to the end portion the needle tip projects from, and the circular rim or edge is arranged inside the outer cylindric body.

The invention provides the following advantages, with respect to the prior art.

Firstly, the device according to the present invention allows to accurately adjust the needle penetration depth, without the need of performing manual controlling operations by the operator.

Secondly, the provision of throughgoing microholes or any other throughgoing holes, through the end tapering portion of the device, allows to prevent any suction effect due to the pressure difference between the inside of the tapering portion and the outer atmospheric pressure, thereby allowing air to outflow.

Thus, the syringe will be prevented from adhering to the skin of the patient by its end tapering portion, which would compel the operator to forcibly detach the syringe from the patient.

This suction cup effect would be particularly dangerous in all those cases in which the medical treatment provides a plurality of

subsequent injections.

Moreover, the use of a suitably contoured surface, to be slightly pressed against the skin of the patient, will allow to sensitize the region encompassing the needle puncture region, thereby the slight pain feeling affecting the patient during the intradermal injection will be further diluted or reduced, to assure, mainly in a case of a plurality of subsequent injections, a greater pain release for the patient.

Finally, the device according to the present invention can be easily constructed by using easily commercially available elements and materials and, moreover, said device can be used with existing syringes.

BRIEF DESCRIPTION OF THE DRAWINGS

Further advantages and characteristics of the present invention will become more apparent hereinafter from the following disclosure, given by way of an illustrative but not limitative example, with reference to the accompanying drawings, where:

Figure 1 is a partially cross-sectioned side view of the device for controlling the penetration depth of a needle according to the present invention, and of a syringe the device is associated with;

Figure 2 is a side view of the syringe assembly fitted to the device for controlling the needle penetration depth;

Figure 3 is a partially cross-sectioned view, on an enlarged scale, of the subject device for

controlling the penetration depth of a needle;
and

5 Figure 4 is a further partially cross-sectioned view, on an enlarged scale, of the subject device for controlling a needle penetration depth, during the carrying out of an intradermal or intracutaneous injection.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

10 In the following disclosure reference will be made to a preferred embodiment of the invention, which will be illustrated as a not limitative example of several possible variations of the invention.

15 Figure 1 is a partially cross-sectioned view illustrating the device for controlling the penetration depth of a needle according to the present invention, said device being generally indicated by the reference number 1, this figure further showing a syringe 4 to which said device 1 is 20 coupled.

25 The device 1, specifically designed for application to said intradermal injection syringe 4, comprises a skin contacting element specifically designed for contacting the skin 8 of a patient, said skin contacting element holding therein a needle 3.

Said skin contacting element 8 comprises a cylindric portion, defining an outer cylindric body 5, and ending with a tapering or conic portion 2.

30 The tapering portion 2 encompasses the tip of the needle 3 and has, at said needle 3 tip, a surface 20.

Preferably, said surface 20 has a

substantially spheric cap configuration, and its concavity is facing the tip of the needle 3.

Moreover, said needle 3 tip projects, for a short length, from the surface 20.

5 Inside the outer cylindric body 5 an inner cylindric body 6 is provided, which is substantially coaxial to said outer cylindric body 5.

10 The inner cylindric body 6 supports the needle 3 and is provided with a circular rim or edge 9, opposite to the end therefrom projects the tip of the needle 3, and which is arranged inside the outer cylindric body 5.

15 Moreover, said tapering portion 2 is provided with a plurality of throughgoing microholes 7 passing through the surface 20.

The device 1 for controlling the penetration depth of a needle according to the present invention operates as follows.

20 More specifically, the device 1 is applied to contact the skin 8 of the patient, i.e. such that the edge of the surface 20 would be brought into contact with the patient skin 8.

25 In this position, the device 1 is slightly pressed to cause the skin 8 to be slightly deformed in order to allow the needle 3 to enter the skin for a set length.

30 Then, the substance held in the syringe 4 will be injected into the patient skin 8, according to a per se known manner, by pressing on the syringe 4 plunger.

Upon ending the intradermal injection, the device 1 will be moved away from the patient skin 8

thereby allowing the skin to resiliently recover to its starting configuration, to favor the injected substance to be easily absorbed by the derma and, then, in the blood system.

5 In this connection it should be pointed out that the provision of the above mentioned microholes 7, or any other throughgoing holes, through the tapering portion 2 of the device 1 will prevent any suction cup effect due to a pressure difference
10 between the inside of the tapering portion 2 and the outer atmospheric pressure from occurring.

15 In fact, said microholes 7, or any other types of throughgoing holes to be formed through the tapering portion 2, will allow air to outflow as the intradermal injection is carried out.

20 Thus, the syringe 4 will be prevented from adhering to the patient skin with its end tapering portion 2, which adhesion would compel the operator to forcibly detach the syringe from the skin of the patient.

25 The mentioned suction cup effect would be particularly dangerous in those cases in which the treatment would provide a plurality of subsequent injections.

30 Moreover, since the edge or rim of the surface 20 is slightly pressed against the skin 8 of the patient, this would allow the area encompassing the needle 3 puncture to be sensitized thereby the slight pain feeling affecting the patient during the intradermal injection will be further reduced, while assuring a greater pain release to the patient, mainly in the case of repeated injections.

CLAIMS

1. A device for controlling the penetration depth of a needle, for application to an injection syringe, characterized in that said device comprises a skin contacting element, said skin contacting element including a surface encompassing, at least partially, the tip of said needle, and in that said skin contacting element is operatively associated with coupling means for connection with said syringe.

2. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to Claim 1, characterized in that said skin contacting element comprises an end tapering portion ending with said surface.

3. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to Claim 1 or 2, characterized in that said surface has a spheric cap configuration and presents the concavity thereof facing the tip of the needle.

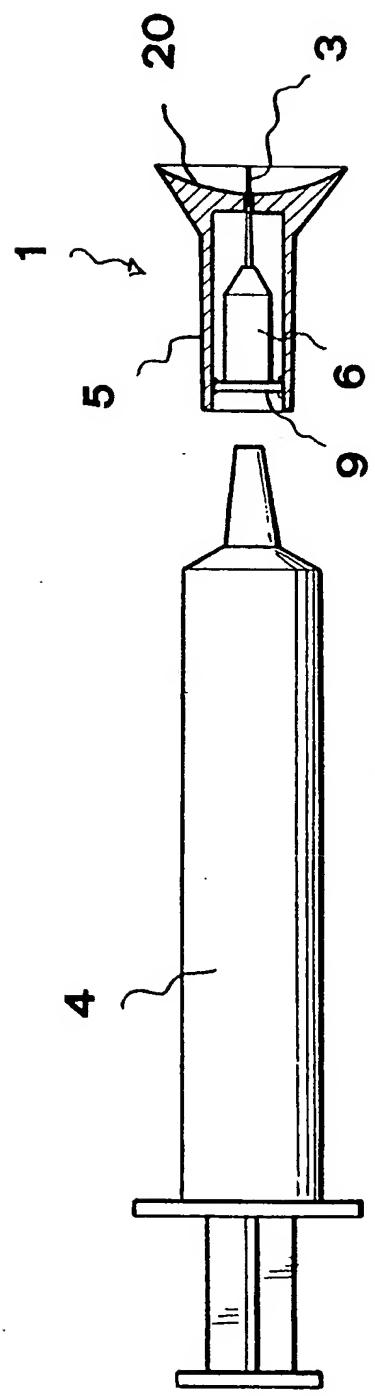
4. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to one or more of the preceding claims, characterized in that said tip of said needle projects for a short length from said surface.

5. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to one or more of the preceding claims, characterized in that said tapering portion comprises a plurality of throughgoing microholes passing through said surface.

6. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to one or more of the preceding claims, characterized in that said means for coupling said skin contacting element to said syringe comprise an outer cylindric body ending with said tapering portion and an inner cylindric body, substantially coaxial to said outer cylindric body and supporting said needle.

10 7. A device for controlling the penetration depth of a needle, for application to an injection syringe, according to Claim 6, characterized in that said inner cylindric body is provided with a circular rim, opposite to the end portion therefrom said tip of said needle projects, wherein said circular rim is arranged inside said outer cylindric body.

1/2



1

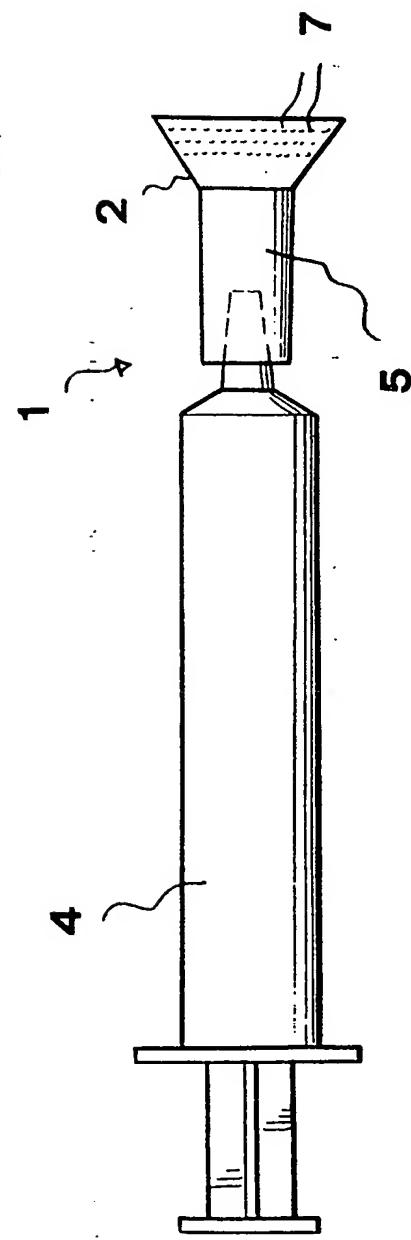


FIG. 2

2/2

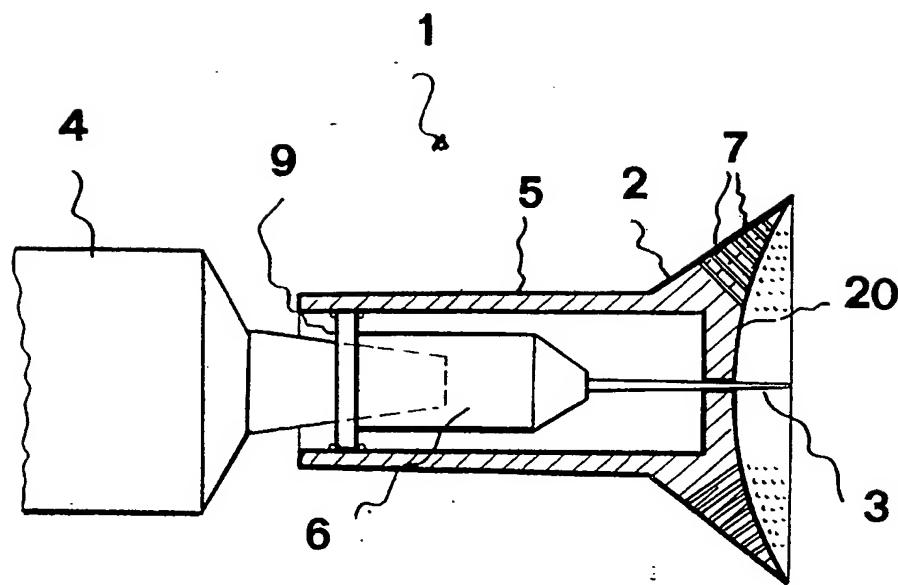


FIG. 3

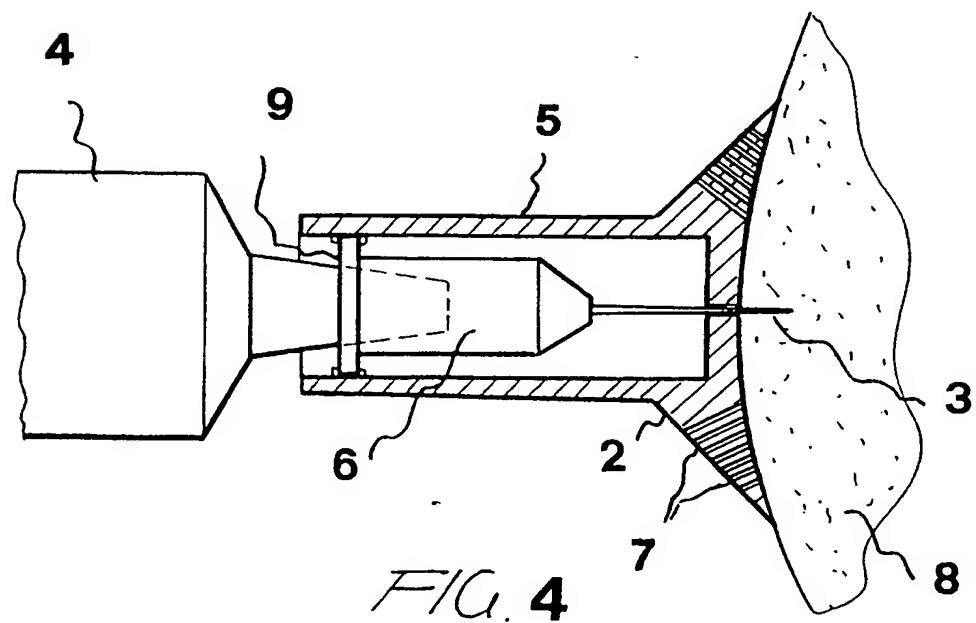


FIG. 4

INTERNATIONAL SEARCH REPORT

Inte
onal Application No
PCT/IT 98/00262

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 A61M5/46		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 6 A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 400 715 A (PEDERSON) 10 September 1968 see column 2, line 10 - line 14; claims 1,2; figures 1,3,4 --- X	1,3
Y	WO 95 01198 A (PARK) 12 January 1995 see page 5, line 7 - page 6, line 14; figures 3-7 ---	5
X	US 2 876 770 A (WHITE) 10 March 1959 see column 3, line 56 - line 59; figures 1-4 ---	1,2,4
Y	FR 2 612 401 A (DENANCE) 23 September 1988 see abstract; figures ---	5
A	---	6
	-/-	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		<input checked="" type="checkbox"/> Patent family members are listed in annex.
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
Date of the actual completion of the international search 24 February 1999		Date of mailing of the international search report 03/03/1999
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Sedy, R

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IT 98/00262

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 578 014 A (EREZ URI ET AL) 26 November 1996 see column 4, line 52 - line 61; figure 4A -----	7

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IT 98/00262

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 3400715	A 10-09-1968	NONE			
WO 9501198	A 12-01-1995	KR 9700475 Y	AU 7085594 A		24-01-1997 24-01-1995
US 2876770	A 10-03-1959	NONE			
FR 2612401	A 23-09-1988	FR 2616665 A			23-12-1988
US 5578014	A 26-11-1996	IL 101720 A	IL 104350 A	AU 4221293 A	24-09-1998 10-03-1998 29-11-1993
		EP 0637972 A	WO 9321974 A		15-02-1995 11-11-1993

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.